Application No.: 10/020,389 Docket No.: SPINE 3.0-352

REMARKS

Reconsideration and withdrawal of the rejection of all the claims now in the application (i.e. Claims 1-29) is respectfully requested in view of the foregoing amendments and the following remarks.

Initially, the Examiner indicated that the application was informal because the Declaration originally filed failed to include the citizenship of each inventor. A new Declaration, including the serial number of the application, was filed on April 24, 2003 in response to the Notice of Informal Application received in this office on March 31, 2003. Consequently, applicant believes that the objection to the Declaration listed in the Office Action has been overcome.

The Examiner then went on to reject claims 1-3 and 8 as being anticipated by U.S. Patent No. 4,452,776 to *Refojo*. The Examiner considered that *Refojo* prepared a hydrogel solution by the process listed in column 3, lines 46 onward. Specifically, *Refojo* teaches the steps of placing a solution of monomers with a selected initiator and a selected cross-linking agent in a mold and then freezing the <u>pre-polymer solution</u> in the mold. The monomers are then polymerized in the mold at a controlled temperature of about 30-50°C for 12 to 24 hours. This is following by curing in an oven at about 60-80°C for 5 to 10 hours followed by a 1 hour curing at 90°C. This results in a chemically cross-linked polymer which is then treated with an isotonic saline to remove the solvent and residual monomers.

The present invention relates to forming a solution of a already polymerized non-crosslinked hydrogel material (PVA-117 Kuraray, Japan for example) which is then dissolved in DMSO, placed in a mold and physically cross-linked using a freeze-thaw cycle, see FIG. 3. The semi-crystalline physically cross-linked material is then treated with an ionic solution to increase the rate at which the polymer chains in the amorphous regions of the material are drawn into the crystalline regions (see Paragraphs 19-21). Such chain movement would not occur in the hydrogel of *Refojo* since it is highly chemically cross-linked which high cross-linking prevents the chain mobility necessary for the material to be drawn into the crystalline regions. This is discussed in paragraph 20 of the application. Nowhere in *Refojo* is it taught that the hydrogel polymer should be physically cross-linked nor does *Refojo* teach that physiologic solution can be used to increase the crystallinity of the hydrogel.

Applicant has amended claims 1 and 13 to include the limitation that the hydrogel is made from a polymer (not monomers) which includes physically cross-linking the polymer

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and then treating the polymer with ions which increase the rate at which the polymer chains are drawn to the crystalline regions. The language added to the claims can be found in paragraph 46 of the application.

With regard to the remaining claims which were rejected as being obvious over a combination of *Refojo* and *Molock* or *Suminone*, applicant believes that there is no incentive to combine *Refojo* and these references since there would be no reason to add potassium carbonate to the *Refojo* wash material since the additional ions would have no effect on the highly chemically cross-linked polymer.

Neither *Refojo*, *Molock* or *Suminone* teach or suggest taking a polymer such as a PVA polymer, forming a solution of the polymer, physically cross-linking the solution and then increasing crystallinity by using a physiologic solution, such as a saline solution. Furthermore, none of the prior art teaches the use of potassium carbonate for further increase the crystallinity.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: July 11, 2003

Respectfully submitted

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